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10/687,986	10/17/2003	Nancy Jean Britten	00661.US1	1367

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,986	BRITTEN ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *5-13,29 and 41-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,14-28 and 30-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/15/04,9/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-40), election of ceftiofur hydrochloride as the antibacterial substance, election of Labrafil M-19944CS, which is a polyglycolized glyceride having oleic acid as the main fatty acid component, as the amphipathic oil, and cottonseed oil as the non-aqueous carrier in the reply filed on 2/28/08 is acknowledged. Applicants elect, with traverse, the mammary gland as the single organ. Applicants respectfully suggest that since pharmaceutical composition claims 1-40 have been elected for prosecution, an election of species requirement relating only to claims which have been withdrawn under the restriction requirement is inappropriate.

The traversal is on the ground(s) that, "Applicants elected, with traverse, the mammary gland as the single organ. Applicants respectfully suggest that since pharmaceutical composition claims 1-40 have been elected for prosecution, an election of species requirement relating only to claims which have been withdrawn under the restriction requirement is inappropriate". This is not found persuasive because it is unclear as what the traversal argument is about. Office required species election on claims that were generic. If applicants elected one group, then applicants are required to elect species for generic claims that belongs to that group and not required to elect species that belonged to non-elected species. However, applicants are required to indicate which read on each elected species.

The requirement is still deemed proper and is therefore made FINAL.

Prior art search indicated that the elected species of active ingredient Ceftiofur hydrochloride is not free of prior art. The prior art found has been applied in the rejections below.

Claims 1-48 are pending.

Claims 5-13, 29 have been withdrawn from further consideration as being drawn to non-elected species. The claims 4-13 are drawn to no-elected species of antibacterial substances and hence have been withdrawn as per the election of species practice.

Claims 41-48 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1-4, 14-28 and 30-40 are examined on the merit.

Claim Objections

Claim 25 is objected to because of the following informalities: The claim recites "pegicol." However it is believed that this should be "peglicol." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites limitations that are designated by 'trade marks'. MPEP section 2173.05(w) states that, "[T]he presence of a trademark or trade name in a claim is not, per se, improper under 35 U.S.C. 112, second paragraph, but the claim should be carefully analyzed to determine how the mark or name is used in the claim. It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. See definitions of

trademark and trade name in MPEP § 608.01(v). A list of some trademarks is found in Appendix I. If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name".

Therefore, since the trade marks in the claims corresponds to particular compounds it would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 14-21, 26-30 and 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,902,683 issued to Amin.

In the instant invention applicants claim a pharmaceutical composition comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b)

microcrystalline wax, and (c) a pharmaceutically acceptable non-aqueous carrier, said vehicle having stably dispersed therein an antibacterial substance in an antibacterially effective amount.

Reference of Amin teaches a composition comprising of crystalline ceftiofur hydrochloride the elected antibiotic compound, cotton seed oil (examples 12-15) which is the elected non-aqueous carrier, cotton seed oil glyceryl mono stearate an amphipathic oil (example 12 or 14) and carnauba wax or white wax which is a microcrystalline wax (example 13 or 15). This meets the limitations of claims 1, 14, 15, 19-21, 26-28. The reference of Amin also teaches a range of 1 to 100 g of ceftiofur ingredient in 1000ml of cottonseed oil glyceryl monostearate (example 12). This results in 1 to 100 mg/ml and the amphipathic oil concentration to >90% hence meets the limitations of instant claims 16-18 and 30. The cited reference also teaches that 1-100 g of ceftiofur ingredient in 1000ml of cottonseed oil (example 13) which results in cottonseed oil concentration ~90% of the composition. This meets the range limitations for cotton seed oil in the instant claims 36-39. The cited reference also teaches the use of magnesium stearate 9example 19) and benzyl alcohol (examples 12-15) that meets the limitations of instant claim 40 as benzyl alcohol is a derivative of benzoic acid recited in the instant claim 40. The claims 2-4 recite an intended use for the composition and hence do not carry patentable weight, see MPEP section 2106 that states, "[T]he subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question

as to the limiting effect of the language in a claim:

(A) statements of intended use or field of use,

(B) "adapted to" or "adapted for" clauses,

(C) "wherein" clauses, or

(D) "whereby" clauses".

Thus the cited reference of Amin anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-25 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,902,683 issued to Amin as applied to claims 1-4, 14-21, 26-30 and 36-40 above, and further in view of US 5,338,761 issued to Nakajima.

In the instant invention applicants claim a pharmaceutical composition comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax, and (c) a pharmaceutically acceptable non-aqueous carrier, said vehicle having stably dispersed therein an antibacterial substance in an antibacterially effective amount.

Reference of Amin teaches a composition comprising of crystalline ceftiofur hydrochloride (cephalosporin) the elected antibiotic compound, cotton seed oil (examples 12-15) which is the elected non-aqueous carrier, cotton seed oil glyceryl mono stearate an amphipathic oil (example 12 or 14) and carnauba wax or white wax which is a microcrystalline wax (example 13 or 15). This meets the limitations of claims 1, 14, 15, 19-21, 26-28. The reference of Amin also teaches a range of 1 to 100 g of ceftiofur ingredient in 1000ml of cottonseed oil glyceryl monostearate (example 12). The reference also teaches the use of lipids in the composition (column 6, line 28). This results in 1 to 100 mg/ml and the amphipathic oil concentration to >90% hence meets the limitations of instant claims 16-18 and 30. The cited reference also teaches that 1-100 g of ceftiofur ingredient in 1000ml of cottonseed oil (example 13) which results in cottonseed oil concentration ~90% of the composition. This meets the range limitations for cotton seed oil in the instant claims 36-39. The cited reference also teaches the use of magnesium stearate 9example 19) and benzyl alcohol (examples 12-15) that meets the limitations of instant claim 40 as benzyl alcohol is a derivative of benzoic acid recited in the instant claim 40. The claims 2-4 recite an intended use for the composition and hence do not carry patentable weight, see MPEP section 2106 that states, "[T]he subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a

particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question
as to the limiting effect of the language in a claim:

(A) statements of intended use or field of use,

(B) "adapted to" or "adapted for" clauses,

(C) "wherein" clauses, or

(D) "whereby" clauses".

The reference of Amin does not teach the polyglycolized glyceride that comprises a main fatty acid component of oleic acid and concentration ranges of amphipathic oil and microcrystalline wax.

The reference of Nakajima teaches the composition of cephalosporin (column 2, line 55) comprising lipids that include POE esters such as POE glycerin fatty acid esters such as POE monooleate, POE dioleate, polyglycerol fatty acid ester such as decaglycerine dioleate (column 3, lines 16-27). This reads on instant claims 23-25). According to MPEP section 2144.05, "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Hence optimization of concentration of amphipathic oil and wax will not support patentability as claimed in the instant claims 31-35.

It would have been obvious to one skilled in the art to modify the teachings of Amin to combine the teachings of Nakajima to arrive at the instantly claimed composition for Ceftiofur hydrochloride. One would have been motivated to do so given the fact that Amin teaches

cottonseed oil glyceryl monostearate and lipid and Nakajima teaches the use of POE glycerin fatty acid esters such as POE monooleate, POE dioleate, polyglycerol fatty acid ester such as decaglycerine dioleate that belongs to the class of lipids and hence one would be motivated to substitute one type of lipid with the other. There would have been reasonable expectation of success given the fact that both Amin and Nakajima were successful in preparing the composition for Ceftiofur hydrochloride.

Thus the invention as a whole was clearly prima facie obvious to one skilled in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 21, 26 and 30-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant invention applicants claim a pharmaceutical composition comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax, and (c) a pharmaceutically acceptable non-aqueous carrier, said vehicle having stably dispersed therein an antibacterial substance in an antibacterially effective amount.

The claims as recited is drawn to an amphipathic oil that has been defined in the specification as "The term "amphipathic oil" is defined as a substance with a distinctly polar region and a distinctly non-polar region. Structurally these two regions of the amphipathic oil are sufficiently far apart that the unique properties of the two regions are distinctly separate [0126]". Thus the genus of the amphipathic oil includes any and all known and unknown molecules that comprises of a polar and a non-polar regions. The specific examples in the specification discloses a trademark named ingredient Labrafil™ M-1944CS, whose chemical composition is unavailable.

The claims as recited is drawn to non-aqueous carrier that has been defined in the specification as "[P]harmaceutically acceptable non-aqueous carriers of the invention can be fully saturated, or partially or fully unsaturated. Examples of non-aqueous carriers include, but are not limited to, vegetable oils (such as cottonseed oil, corn oil, sesame oil, soybean oil, olive oil, fractionated coconut oils, peanut oil, sunflower oil, safflower oil, almond oil, avocado oil, palm oil, palm kernel oil, babassu oil, beechnut oil, linseed oil, rape oil, and the like), mineral oils, synthetic oils, and combinations thereof. Examples of fully saturated non-aqueous carriers include, but are not limited to, esters of medium to large chain fatty acids (such as fatty acid triglycerides with a chain length of about C6 to about C24). Mixtures of fatty acids are split from the natural oil (for example coconut oil palm kernel oil, babassu oil, or the like) and are refined. In some embodiments, about C8 to about C12 fatty acid medium chain triglycerides are useful. An illustrative saturated non-aqueous carrier comprises capric acid (about 20% to about 45% by weight of the carrier) and caprylic acid (about 45% to about 80% by weight of the carrier). Other fully saturated non-aqueous carriers include, but are not limited to, saturated coconut oil (which typically includes a mixture of laurie, myfistic, palmitic, capric and capric acids), including those sold under the Miglyol TM trademark from Huls and beating trade designations 810, 812, 829, and 840). Also noted are the

NeoBee TM products sold by Drew Chemicals. Isopropyl myristate is another example of a non-aqueous carrier useful in compositions of the invention. Examples of synthetic oils include triglycerides, and propylene glycol diesters of saturated or unsaturated fatty acids having from 6 to 24 carbon atoms such as, for example hexanoic acid, octanoic (caprylic), nonanoic (pelargonic), decanoic (capric), undecanoic, lauric, tridecanoic, tetradecanoic (myristic), pentadecanoic, hexadecanoic (palmitic), heptadecanoic, octadecanoic (stearic), nonadecanoic, heptadecanoic, eicosanoic, heneicosanoic, docosanoic, and lignoceric acids, and the like. Examples of unsaturated carboxylic acids include oleic, linoleic, and linolenic acids, and the like. It is understood that the non-aqueous carrier can comprise the mono-, di-, and triglyceryl esters of fatty acids or mixed glycerides and/or propylene glycol diesters wherein at least one molecule of glycerol has been esterified with fatty acids of varying carbon atom length. A non-limiting example of a "non-oil" of the present invention is polyethylene glycol [0135]". However, the specific examples in the specification discloses only one non-aqueous carrier which is cottonseed oil. Mere recitation of numerous compounds that belongs to several genera of compound classes does not satisfy the written description to a generic claim.

With regards to microcrystalline wax, applicants have not provided a proper definition. Applicants defer the definition to a Handbook f pharmaceutical excipients or as defined in National formulatary [0133]. Applicants have neither provided relevant information in the form of prior art reference nor listed the reference in the IDS with relevant information available for consideration.

With respect claim 14 wherein applicants have listed numerous compounds belonging to the genus of cephalosporin, the specific examples in the specification discloses only Ceftiofur hydrochloride.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient" MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated: "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . "). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

Thus the claims as recited is not adequately supported by the specification to commensurate with the scope of the claim in terms of providing representative number of specific examples that define the instant invention.

Therefore, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654